ETHIC Act Statement for Record: Dr. Rachel Goode, SVP, IP and Legal, Fresenius Kabi Biopharmaceuticals

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U.S. House Judiciary Committee's Subcommittee on Courts, Intellectual Property, and the Internet during its hearing on "Medicines and IP: Balancing Innovation and Access" During the hearing statements were made by witnesses that Fresenius believes to misleading or untrue. We will address these statements for the record as well as answer questions posed by the chairman for our consideration.

Misleading Witness Statements:

1. The USPTO issued a report that proves that exclusivity periods and the number of litigated patents have remained stable over time.
2. There is no empirical evidence that proves patent thickets exist.
3. The ETHIC Act would harm small biotech companies
4. The ETHIC Act would relinquish investment to China.
5. Terminally Disclaimed continuation patents contain independently novel claims compared with each other.
6. The ETHIC Act limits enforcement of incremental improvements to old drugs.
7. The Affordable Prescriptions for Patients Act is the answer to patent thickets.
8. The ETHIC Act violates the takings clause.
9. The ETHIC Act is not needed because generics already make up 90% of the prescriptions filled today in the U.S.
10. The ETHIC Act does not provide sufficient flexibility for patent owners who later obtain additional information about a generic or biosimilar product or its manufacturing process.

Questions posed by Chairman Issa:

1. Would a manufacturing waiver similar to the EU's SPC waiver encourage more U.S. manufacturing of generics and biosimilars?
2. What impacts exist for the generics and biosimilars industries given the behavior of the USPTO in instituting IPR/PGRs?

Congress Should Not Rely on the USPTO Report to Assess Modern Patent Thicketing

The witness's claim that patent litigation against generics and biosimilars "remained stable" from 2018–2022 is misleading. That conclusion relies on a USPTO report that was not peer reviewed and is based on a limited, selectively chosen set of largely outdated cases.[1] The report focuses primarily on litigation involving drugs approved before 2010, before patent thickets and extensive continuation patenting became widely used strategies for delaying generic and biosimilar competition. As a result, it does not provide an accurate picture of current patenting and litigation practices.

The USPTO report excludes biologic medicines entirely, despite the fact that many of the most significant concerns about patent thickets arise in the biologics space. The report also relies on a highly selective sample that includes products such as aspirin while omitting important patents covering major drugs like Imbruvica. Moreover, the report itself acknowledges that its sample size is too small to support broad conclusions about industry-wide trends.

Taken together, these methodological flaws mean the report does not provide a reliable picture of current pharmaceutical patenting practices and would be unlikely to withstand rigorous peer-review scrutiny. Congress should instead rely on comprehensive, peer-reviewed evidence when assessing the impact of patent thickets on competition, drug prices, and patient access.

Peer-Reviewed Evidence Demonstrates That Patent Thickets Delay Competition and Patient Access

Congress should rely on rigorous, peer-reviewed evidence when evaluating pharmaceutical patent policy. Peer review provides transparency, allows independent scrutiny of methodology, and helps ensure that policy decisions are based on reliable data rather than selective or anecdotal examples.

The peer-reviewed evidence consistently shows that the United States experiences substantially greater duplicative patenting and longer delays to biosimilar competition than comparable jurisdictions. One study examining all FDA-approved biosimilars

[1] United States Patent and Trademark Office. (2023). Drug Patent and Exclusivity Study: Report to Congress. Retrieved from https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf

found that the same products faced 344 asserted patents in the United States, compared with 46 in Canada and 24 in the United Kingdom. While biosimilars were delayed by an average of only five months in the UK and seven months in Canada, delays in the United States averaged two years and ten months.[2]

Peer-reviewed research has also documented the strategic use of terminally disclaimed patents to disrupt business certainty of biosimilar competitors. An analysis of terminal disclaimer filings found a dramatic concentration of patent issuances around the twelfth year after approval of branded biologic medicines—the precise point at which FDA regulatory exclusivity expires. The scale and timing of these filings strongly suggest that terminal disclaimers are being used to extend uncertainty and delay biosimilar market entry at the moment competition would otherwise be expected to occur.[3]

Peer-reviewed research demonstrates that the use of duplicative patents in biologics has increased substantially over time. One study examining litigated biologic patents listed in the Purple Book found that 35% of patents filed between 2003 and 2013 were duplicative. For patents filed between 2014 and 2020 that were later asserted against biosimilar competitors, that figure rose to 98%.[4] This sharp increase suggests that duplicative patenting has become an increasingly common strategy in biologic drug markets. Importantly, peer-reviewed studies have also documented patent thicketing practices in the small-molecule pharmaceutical sector, demonstrating that these concerns extend beyond biosimilars and affect generic drug competition as well.[5]

Importantly, these findings are not isolated. Dozens of peer-reviewed studies have independently documented the increasing use of continuation patents, terminal disclaimers, and other patenting strategies that can delay generic and biosimilar competition. Congress should therefore place greater weight on the growing body of peer-reviewed evidence, which provides a comprehensive and transparent assessment of current patenting practices and their impact on competition, drug prices, and patient access.

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[2] Rachel Goode, Bernard Chao, Biological patent thickets and delayed access to biosimilars, an American problem, *Journal of Law and the Biosciences*, Volume 9, Issue 2, July-December 2022, lsac022, https://doi.org/10.1093/jlb/lsac022

[3] Tu SS, Goode R, Feldman WB. Biologic Patent Thickets and Terminal Disclaimers. JAMA. 2024;331(4):355–357. doi:10.1001/jama.2023.25389

[4] Carrier, M. A., & Tu, S. S. (2023). Why pharmaceutical patent thickets are unique. Texas Intellectual Property Law Journal, 32(1), 79–110. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4571486

[5] Tu SS, Kesselheim AS, Wetherbee K, Feldman WB. Changes in the Number of Continuation Patents on Drugs Approved by the FDA. JAMA. 2023 Aug 1;330(5):469-470. doi: 10.1001/jama.2023.11525. PMID: 37526728; PMCID: PMC10394575

The ETHIC Act does not harm small biotech companies

The ETHIC Act does not harm small biotechnology companies because it does not affect genuine innovation nor the patents that protect scientific breakthroughs. Innovation is driven by new discoveries, not by the accumulation of duplicative patents, and venture capital investment in biotechnology is based on the strength of those underlying innovations. The ETHIC Act preserves and protects valid patents, ensuring that innovators continue to receive the rewards intended by the patent system.

In practice, many biotechnology companies develop promising therapies and then license or sell those assets to larger pharmaceutical companies before the most expensive stages of clinical development and commercialization. The value of those transactions depends on the quality and validity of the underlying patents, not on the later proliferation of duplicative patents. The conduct targeted by the ETHIC Act typically occurs much later in a product's lifecycle, after launch, when branded pharmaceutical companies obtain and assert large numbers of overlapping patents that create uncertainty and delay competition.

The concerns driving patent reform are therefore not directed at biotechnology innovators. They are directed at the use of duplicative patents to shield weak or invalid patents from efficient challenge and to delay patient access to lower-cost medicines. By preserving strong protection for genuine inventions while discouraging patent system abuse, the ETHIC Act strengthens confidence in the patent system and ensures that rewards flow to true innovation rather than to the strategic accumulation of redundant patents.

The ETHIC Act Helps America Out-Innovate China Through Stronger Patents, Not More Patents

America's innovation leadership should be measured by the quality of its patents, not the quantity. The ETHIC Act strengthens U.S. competitiveness by encouraging companies to invest in genuinely new inventions rather than accumulating duplicative patents covering the same innovation.

By limiting the litigation advantages associated with duplicative patents, the ETHIC Act creates stronger incentives for branded pharmaceutical companies to develop additional, distinct inventions if they want a larger portfolio of patents to assert. In this way, the Act promotes more innovation in America, not less. At the same time, it helps clear duplicative patents from the US patent system, reducing clutter and improving transparency for innovators, investors, and competitors alike.

As the United States competes with China in the global innovation race, success should be defined by the creation of high-quality inventions and strong patents—not

by the accumulation of redundant ones. The ETHIC Act reinforces that principle and strengthens the long-term health of the American innovation ecosystem.

Terminally Disclaimed continuation patents do not contain independently novel claims compared with each other.

Some have argued that the ETHIC Act would incentivize branded pharmaceutical companies to avoid filing terminal disclaimers and instead seek patents with later expiration dates. This claim misunderstands how patent law operates. Absent a terminal disclaimer, duplicative patents would not grant, as they would violate well-established double-patenting rules. In practice, terminal disclaimers are filed in response to, or in anticipation of, patent office rejections where claims are not meaningfully distinct from an existing patent.

Importantly, the foundational patent in a terminally disclaimed family—the parent patent—already reflects a bona fide incremental innovation, having met the statutory requirements of novelty and non-obviousness over prior art. Subsequent patents in the family do not extend that innovation; they merely replicate it, sharing the same priority filing and expiration date. Because they are examined against the same prior art date, any truly novel and non-obvious claims would qualify for an independent 20-year term. The absence of such claims demonstrates that these patents are substantively duplicative, with only minor linguistic variations rather than meaningful scientific distinctions.

In MPEP § 201.07 (implementing 37 CFR 1.78) that makes clear a continuation application must not add new matter:

- "A continuation application is an application for the invention(s) disclosed in a prior-filed copending … application. **The disclosure presented in the continuation must not include any subject matter which would constitute new matter if submitted as an amendment to the parent application.**" [bitlaw.com]
- Obviousness-type double patenting prevents an applicant from obtaining a second patent with claims that, based on their claim language, are not patentably distinct because they are merely an obvious variation of claims in an earlier patent. Under 37 CFR § 1.321(c), applicants must file a terminal disclaimer to obviate such rejections.

The ETHIC Act does not undermine innovation—it curbs gamesmanship. By removing incentives to accumulate redundant patents that offer no new therapeutic benefit, the Act reinforces the principle that patent protection should correspond to genuine scientific advancement. In doing so, it strengthens the integrity of the patent system and better aligns it with patient and public interest.

The ETHIC Act Does Not Limit Enforcement of Unique Patents as New Information Emerges

Some have argued that patent owners cannot always identify every relevant patent at the outset of litigation because they may not yet have complete information about a generic or biosimilar manufacturer's product or manufacturing process. However, that concern is not relevant to the ETHIC Act.

The ETHIC Act does not limit the number of unique patents that may be asserted. If additional information becomes available during litigation and reveals that another distinct patent is relevant, that patent can still be asserted. The Act therefore preserves full protection for genuine inventions and does not prevent patent owners from enforcing newly identified patent rights as facts emerge.

What the ETHIC Act limits is the ability to multiply litigation through duplicative patents covering the same invention. If multiple patents contain substantially similar claims, those claims can be consolidated into a single patent without any loss of substantive patent protection. A patent owner retains the same ability to protect its invention, but without creating unnecessary complexity, costs, and delay through the assertion of multiple duplicative patents.

In short, the ETHIC Act does not prevent patent owners from enforcing legitimate patents that become relevant later in a case. It simply ensures that patent protection is based on distinct inventions rather than redundant patents covering the same subject matter.

The Affordable Prescriptions for Patients Act Does Not Address the Root Cause of Patent Thickets

While the bill represents an acknowledgment that patent thickets are a problem, it does not reduce the gamesmanship that delays generic competition. The bill imposes a numerical limit on the number of patents that may be asserted against a generic drug, but that limit is subject to numerous exceptions and procedural conditions. Certain categories of patents, including method-of-treatment patents and some device-related patents, may still be litigated in addition to the cap, and the bill does not address biologic medicines, where many of the most significant patent thickets exist today. Moreover, generic manufacturers can lose the benefit of the cap through procedural missteps, creating additional uncertainty and complexity.

More fundamentally, the bill does not address the underlying incentive that drives patent thicketing—the ability to obtain and assert large numbers of duplicative patents covering the same invention. As a result, it manages the symptoms of the

problem rather than eliminating the source of it. It also does little to strengthen incentives for genuine innovation because it focuses on litigation mechanics rather than patent quality.

By contrast, the ETHIC Act directly targets the root cause of patent thickets by discouraging the proliferation of duplicative patents while preserving full protection for valid inventions and true scientific breakthroughs. It offers a simpler, more durable, and more innovation-focused solution. Rather than creating new procedural rules and exceptions, the ETHIC Act aligns patent incentives with the original purpose of the patent system: rewarding innovation, not the accumulation of redundant patents.

The ETHIC Act Is a Constitutional Guardrail Against Patent Abuse, Not a Taking of Property

The claim that the ETHIC Act is unconstitutional is not supported by existing law. Patents are government-created rights, and courts have repeatedly recognized Congress's authority to define their scope and enforcement. The Supreme Court and Federal Circuit have upheld significant limitations on patent rights, including the cancellation of issued patents, without requiring compensation. Courts have also consistently recognized that reasonable limits on patent litigation do not constitute a taking under the Constitution.

The ETHIC Act does not impose a hard cap on patents, revoke valid patents, or eliminate protection for genuine inventions. Instead, it preserves full protection for every patentably distinct innovation while reducing the ability to multiply litigation through duplicative patents. In doing so, it advances due process by helping courts identify the truly relevant patents at the outset of litigation, rather than spending years narrowing sprawling patent disputes. The ETHIC Act is not a taking of property—it is a reasonable and constitutional safeguard against abuse of the patent system.

90% of Prescriptions Are Generic: The Issue Is Not Whether Competition Occurs, It Is How Long Competition Is Delayed

The fact that generic medicines account for roughly 90% of prescriptions today does not mean patent thickets are not delaying competition. The question is not whether generic entry eventually occurs—it is when it occurs. Patents are not perpetual, and most generic and biosimilar competitors ultimately reach the market. The problem is that many are arriving years later than they otherwise would because of duplicative patenting and litigation strategies.

Those delays matter. If generic and biosimilar competition had begun earlier, patients, employers, and taxpayers would have realized billions of dollars in additional savings.

Moreover, the 90% figure largely reflects low-cost commodity generic markets. The greatest spending in the U.S. healthcare system is concentrated in the remaining 10% which is a relatively small number of high-cost drugs[6], where patent thickets are most prevalent and where delays to competition have the greatest financial impact.

Questions Posed by Chairman Issa:

Would a U.S. Manufacturing Waiver, Similar to the EU Waiver, Bring Biosimilar Manufacturing Investment to the U.S.?

International patent rules under the TRIPS Agreement give patent owners strong protection. For at least 20 years, the patent holder can stop others from making, using, selling, or exporting the patented product. For pharmaceuticals, this protection is often extended in Europe through Supplementary Protection Certificates (SPCs), which can add up to five more years of exclusivity to make up for time lost in regulatory approval.

The European SPC waiver allows generic and biosimilar companies in Europe to manufacture medicines during the SPC period. However, it does not permit infringing manufacturing activities during the 20-year patent term period. Under the EU SPC waiver, generic drugs and biosimilars may be produced for export to countries where patent protection has already ended. They may also be manufactured during the last six months of the SPC so the product can be launched in Europe immediately once the SPC expires.

The policy reason for this waiver in Europe is practical and economic. Before the waiver, European manufacturers were not allowed to produce at all during the SPC period, even for export, while companies outside the EU could. This put EU companies at a disadvantage and encouraged manufacturing to move outside Europe.

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[6] Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis

The waiver is meant to fix that problem without taking away the patent holder's core rights. No manufacturing can take place during the 20-year patent term, which is required under the TRIPs Agreement.

In the United States, pharmaceutical patents can also be extended by up to five years. Each drug is eligible for a single extension for one of its patents, known as a patent term extension, which is broadly equivalent to a European SPC. Unlike in Europe, the United States does not permit manufacturing during the patent term extension (PTE) period. Even if it did, we do not believe this would meaningfully increase U.S. manufacturing of generic drugs and biosimilars, because the U.S. patent landscape is far more crowded, with many more overlapping patents ("patent thickets") than in Europe. In any event, the TRIPS Agreement does not permit manufacturing during the term of the underlying patents themselves.

Further, although this may allow U.S. manufacturing, it does nothing to get cheaper drugs on the market at an appropriate time. Therefore, the manufacturing issue is better solved by passing the ETHIC Act. If biosimilars are significantly delayed compared to other developed countries, the U.S. market cannot support biosimilar manufacturing as the cost to manufacture in the U.S. would have to be balanced against the delay in market formation.

IPRs Enable Early Biosimilar Entry and Lower Drug Costs, But Their Impact Is Being Severely Undermined, What is the Practical Impact to Biosimilar Manufacturers?

The claim that IPRs do not help biosimilars or generic drugs access the market is not supported by the evidence. There are clear, real-world examples showing the opposite.

For example, Fresenius Kabi developed and launched a biosimilar to Actemra, a drug used to treat autoimmune diseases and, more recently, COVID-19. They filed inter partes review (IPR) challenges against five patents covering this product, and all were successfully instituted.[7] As a result, Fresenius Kabi was able to launch our biosimilar in April 2024, eight years before the expiry of the last asserted patent. At the time of launch, court litigation had only just begun, so it was the IPR process that enabled this significantly earlier patient access, well before traditional litigation would have cleared a path.

This is not an isolated example. Empirical research by Professor Charles Duan identifies multiple case studies in which generic drugs entered the market rapidly after successfully challenging invalid patents through IPRs, rather than waiting for

[7] https://www.bigmoleculewatch.com/ptabtracker/

protracted court proceedings.[8] His paper shows that in each case, generic entry led to substantial reductions in drug prices, demonstrating the direct link between IPRs, market entry, and affordability.

These outcomes reflect the structural advantages of IPRs. They provide a faster and more expert forum for assessing patent validity, with technical judges and the ability to test evidence through expert submissions and cross-examination. This makes them a particularly effective tool for clearing weak or invalid patents that would otherwise delay competition.

However, despite their importance, IPRs are becoming increasingly inaccessible. Institution rates have dropped sharply, from around 61% between January and August 2024 to approximately 28% between October 2024 and August 2025. Concerningly, the number of petitions filed per month has declined significantly over the same period. These trends are largely driven by sweeping discretionary denials based on policies that were implemented without formal rulemaking.

There is also a troubling increase in denials on the merits that are issued without any substantive explanation. In these cases, the only indication of the decision is that the patent appears on a list of IPRs denied "on the merits," with no reasoning provided. In practice, these decisions closely resemble discretionary denials, raising concerns that this classification may be used to make discretionary denial statistics appear more favorable.

The practical impact is significant. Generic and biosimilar companies are now being advised by counsel to avoid filing IPRs altogether. This is because even a denial, regardless of the underlying reasoning, can be used by branded drug companies to suggest that a patent is strong on its merits, potentially influencing how courts perceive the patent in litigation.

As a result, one of the most effective mechanisms for enabling timely biosimilar and generic entry is being undermined. If the goal is to improve patient access to lower-cost medicines, the availability of IPRs must be restored in line with the statute.

[8] American University. Law Review. 72 Am. U. L. Rev. 1177 (2023). On the Appeal of Drug Patent Challenges Author: Charles Duan